DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-22BG]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Triazole-resistant Aspergillus fumigatus Case Report Form" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on December 21, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Characteristics of Patients with Environmentally-derived Triazole-resistant Aspergillus fumigatus – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The environmental mold *Aspergillus fumigatus* is the primary cause of invasive aspergillosis and is associated with 50% mortality in high-risk patients, including stem cell and organ transplant recipients. The use of triazole antifungals has greatly improved survival, however triazole-resistant *A. fumigatus* infections are increasingly reported worldwide and are associated with increased mortality and treatment failure. Of particular concern are resistant *A. fumigatus* isolates carrying the TR34/L98H and TR46/Y121F genetic resistance markers, which are associated with environmental triazole fungicide use rather than previous patient exposure to antifungals. Infections with these triazole-resistant strains have become common among patients with *A. fumigatus* infections in Europe, Asia, and South America, and have been characterized epidemiologically. However, U.S. reports of isolates carrying TR34/L98H or TR46/Y121F markers are limited, and detailed epidemiologic data are critical to inform public health response.

CDC is already receiving *Aspergillus fumigatus* isolates from laboratories across the nation, primarily through Antibiotic Resistance Laboratory Networks (ARLN) and sometimes directly from submitters. These isolates undergo testing for triazole resistance (defined using minimum inhibitory concentrations or epidemiologic cutoff values set forth by Clinical and Laboratory Standards Institute). For patients involving triazole-resistant isolates, we plan to use a

standardized case report form (CRF) to collect public health surveillance data regarding demographics (e.g., age, sex, race/ethnicity, country of residence), underlying medical conditions, treatments, and outcomes (e.g., vital status at 30 days for initial positive specimen). The CRF would be filled out voluntarily by state and local health departments and contains an optional supplement at the end involving a brief interview (including data on occupational and environmental exposures) of a patient or their representative. The findings would be used to describe the risk factors, clinical features, and outcomes for patients with triazole-resistance Aspergillus fumigatus. U.S. data on triazole-resistant Aspergillus fumigatus are lacking, although this problem constitutes a major public health threat.

CDC requests OMB approval for an estimated eight annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Public Health Officials, Clinicians	Triazole-resistant *Aspergillus fumigatus* Case Report Form	15	1	30/60

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